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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,648	02/12/2007	Masaru Tanaka	4252-0119PUS1	5783

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EXAMINER	
IWAMAYE, ANDREW MICHAEL	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
12/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,648	TANAKA ET AL.	
	Examiner	Art Unit	
	ANDREW IWAMAYE	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,15 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 14-15, 20-23,* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/05/2009 has been entered.

Response to Arguments

2. Applicant's arguments with respect to **claims 11, 14-15, and 20-23** have been considered but are moot in view of the new ground(s) of rejection.

On pp 5 of Applicant's arguments, Applicant argues the rejections with Patel. Specifically Applicant argues that Patel is "directed to a stent having a multiplicity of cell openings **greater than 100 microns in width** which can overcome the issue associated with GORE-TEX Vascular Graft and similar stent covers."

While Applicant may be correct in that the claimed invention of Patel is directed towards a stent with cell openings **greater than 100 microns in width**, there is still a clear and explicit teaching in the disclosure of Patel to use stent covering films having openings of 10-100 microns in order to prevent diseased tissue ingrowth.

Furthermore, Applicant argues that Patel teaches pores greater than 100 microns in width in order to overcome the problems associated with GORE-TEX -- specifically

the problems of inhibited re-endothelialization. However, Patel clearly states: "...due to the very small pore size [of GORE-TEX], re-endothelialization with new healthy tissue may be somewhat compromised. Due to the recitation of "may", there is still a possibility that re-endothelialization can occur. Also, due to the recitation of "somewhat", it is clear that re-endothelialization occurs at least partially. As such, the disclosure of Patel does not even teach away from the use of pores smaller than 100 microns, more specifically 10-100 microns.

Nevertheless, whether or not re-endothelialization occurs is moot, as the fact remains that Patel gives a clear teaching to employ stent films having pore sizes within the claimed range in order to prevent diseased tissue ingrowth.

For at least these reasons, Examiner has maintained the use of Patel in the rejections that follow.

On pp 6 of Applicant's arguments, Applicant argues the rejections to Patel in view of Nishikawa. To sum, Applicant argues that "there must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements of Patel and Nishikawa in the way the claimed new invention does."

Examiner asserts that a reason/motivation was clearly provided in the rejection of the previous Office action. The motivation was as follows: "One would be further motivated to provide the film of Nishikawa since production of such a film is more cost-saving and technologically simpler than other production techniques ("Introduction" section)."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 11, 14-15, and 20-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 6,436,132) in view of Nishikawa et al (*Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces*), hereinafter referred to as N1, and Nishikawa et al (*Fabrication of Honeycomb Film of an Ampiphilic Copolymer at the Air-Water Interface*), hereinafter referred to as N2.

Regarding **claims 11 and 20**, Patel et al (Patel) teaches a **stent** (i.e. **a medical instrument**) **comprising** a stent surface (i.e. **a medical instrument substrate**), **and a** ePTFE covering (i.e. **film**) **including a resin and having a porous structure formed at least on its surface, the surface of the medical instrument being entirely or partially covered with the film** (column 2, lines 19-49), **pores of the porous structure of the film have an average pore size of** 10-100μm (i.e. within the range of **0.1 to 20μm**).

Patel fails to explicitly teach a **honeycomb structure**.

However, N1 teaches a film including a resin and having a **honeycomb** porous structure formed at least on its surface (see "Experimental" section beginning on pp

142). The film can be tailored to inhibit cellular adhesion/proliferation, specifically when the pores sizes are kept at 2microns or below (see pp 145, first paragraph of right column and "Conclusions" section).

Patel and N1 are concerned with the same field of endeavor, namely films that prevent/inhibit cellular growth.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Patel by incorporating a porous film with a honeycomb structure and pore size within the claim range, as taught by N1, in order to provide an alternative, commonly known anti-cell-proliferation film. One would be further motivated to provide the film of N1 since production of such a film is more cost-saving and technologically simpler than other production techniques ("Introduction" section of N1).

Patel and N1 combination also fail to teach the claimed **thickness of the film**.

However, N2 teaches the same films of N1 but further teaches film thicknesses to be 1200nm (or 1.2μm) (see "Control of Film Thickness" section on pp 5736-5738). As such N2 teaches thicknesses within the claimed range.

Patel and N1 combination and N2 are concerned with the same field of endeavor, namely films that prevent/inhibit cellular growth.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Patel and N1 combination by incorporating a thickness within the claimed range, as taught by N2, in order to optimize the effect on

cellular attachment to the solid substrate (see line 18+ of "Conclusion" section of N2 on pp 5740).

Regarding **claim 14**, the surface topographic images of the films in each of N1 and N2 appear to teach the pores to be formed substantially in a uniform manner (see Figures of N1 and N2). Also, N2 clearly teaches pores of the film to have a coefficient of variation in pore size of 30% or less (see measurement values on bottom of left column on pp 5736).

Regarding **claim 15**, The Examiner recognizes claim 15 as a "product-by-process" claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (*In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966).

Since Patel, N1, and N2 combination teach all of the structural limitations, Patel, N1, and N2 combination meet the medical instrument of claim 15

Nevertheless, N1 and N2 teach a film obtained by the claimed production steps (see "Introduction" and "Experimental" sections of N1 and N2).

Regarding **claims 21-22**, Patel, N1, and N2 combination teach all of the structural limitations. As such, the stent of Patel, N1, and N2 combination is inherently capable of being used as a digestive system stent, specifically a bile duct stent.

Regarding **claim 23**, Patel, N1, and N2 combination teach all of the limitations. Refer to rejections as applied to claims supra. Patel further teaches the pores to be through-holes, as cells, tissue, and capillaries can penetrate through the pores to the intima (see column 2, lines 19-49).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW IWAMAYE whose telephone number is (571)270-7036. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner, Art Unit 3774

/A. I./
Examiner, Art Unit 3774
11/19/2009